



### General

### Guideline Title

Evidence-based clinical practice guideline: reduction mammaplasty.

### Bibliographic Source(s)

American Society of Plastic Surgeons. Evidence-based clinical practice guideline: reduction mammaplasty. Arlington Heights (IL): American Society of Plastic Surgeons; 2011 May. 16 p. [33 references]

#### Guideline Status

This is the current release of the guideline.

### Recommendations

### Major Recommendations

Definitions for the levels of evidence (I–V) and the grades of the recommendations (A–D) are provided at the end of the "Major Recommendations" field.

Pre-operative Considerations

Consideration for Surgical Planning

Recommendation: Evidence indicates that resection volume is not correlated to the degree of postoperative symptom relief; thus, the criterion for reduction mammaplasty is more accurately defined by individual symptomatology rather than breast volume alone. Level II Evidence: Grade B

Recommendation: Evidence indicates that increased breast resection weight may increase the risk of complication; therefore, patients should be informed of this potential risk. Level II, III Evidence: Grade B

Recommendation: Evidence is inconclusive on whether increased body mass index (BMI) is associated with increased risk of complications; therefore, the decision to perform reduction mammaplasty on a patient with increased BMI is left to the discretion of the surgeon. *Level II, III Evidence: Grade C* 

#### Treatment

#### Operative Procedures

Recommendation: Evidence indicates that perioperative antibiotics may reduce the risk of infection associated with reduction mammaplasty; thus, surgeons should consider using perioperative antibiotics in reduction mammaplasty patients, taking into account patient risk factors, allergies and

issues of antibiotic resistance. Level II Evidence: Grade C

Recommendation: In standard reduction mammaplasty procedures, evidence indicates that the use of drains is not beneficial. However, if liposuction is used as an adjunctive technique, the decision to use drains should be left to the surgeon's discretion. Level I, II Evidence: Grade A

#### Outcomes

Effectiveness/Quality of Life

Recommendation: Evidence indicates that reduction mammaplasty is effective at reducing breast hypertrophy-related symptoms and improving quality of life. Reduction mammaplasty should be considered for patients with symptomatic breast hypertrophy. Level I Evidence: Grade A

#### <u>Definitions</u>:

Evidence Rating Scale for Therapeutic Studies

| Level of<br>Evidence | Qualifying Studies  |
|----------------------|---|
| I                    | High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or systematic review of these studies                 |
| II                   | Lesser-quality, randomized controlled trial; prospective cohort or comparative study; or systematic review of these studies                             |
| III                  | Retrospective cohort or comparative study; case-control study; or systematic review of these studies  |
| IV                   | Case series with pre/post test; or only post test   |
| V                    | Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or "first principles" |

#### Evidence Rating Scale for Diagnostic Studies

| Level of<br>Evidence | Qualifying Studies  |
|----------------------|---|
| I                    | High-quality, multi-centered or single-centered, cohort study validating a diagnostic test (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies |
| П                    | Exploratory cohort study developing diagnostic criteria (with "gold" standard as reference) in a series of consecutive patient; or a systematic review of these studies                                     |
| III                  | Diagnostic study in nonconsecutive patients (without consistently applied "gold" standard as reference); or a systematic review of these studies  |
| IV                   | Case-control study; or any of the above diagnostic studies in the absence of a universally accepted "gold" standard   |
| V                    | Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or "first principles"   |

#### Evidence Rating Scale for Prognostic/Risk Studies

| Level of<br>Evidence | Qualifying Studies  |
|----------------------|---|
| I                    | High-quality, multi-centered or single-centered, prospective cohort or comparative study with adequate power; or a systematic review of these studies   |
| П                    | Lesser-quality prospective cohort or comparative study; retrospective cohort or comparative study; untreated controls from a randomized controlled trial; or a systematic review of these studies |

| Level of<br>Evidence | Case series with pre/post test; or only post test   |
|----------------------|---|
| V                    | Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or "first principles" |

### Scale for Grading Recommendations

| Grade | Description              | Qualifying Evidence   | Implications for Practice  |
|-------|--------------------------|---|--|
| A     | Strong<br>Recommendation | Level I evidence or<br>consistent findings<br>from multiple studies of<br>levels II, III, or IV | Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.   |
| В     | Recommendation           | Levels II, III, or IV<br>evidence and findings<br>are generally consistent                      | Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences.  |
| С     | Option                   | Levels II, III, or IV<br>evidence, but findings<br>are inconsistent                             | Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.                      |
| D     | Option                   | Level V: Little or no<br>systematic empirical<br>evidence                                       | Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role. |

### Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Female symptomatic breast hypertrophy

Note: Symptomatic breast hypertrophy is defined as a syndrome of persistent neck and shoulder pain, painful shoulder grooving from brassiere straps, chronic intertriginous rash of the inframammary fold, and/or frequent episodes of headache, backache, and upper extremity peripheral neuropathies caused by an increase in the volume and weight of breast tissue beyond normal proportions.

## Guideline Category

Diagnosis

Evaluation

Management

Risk Assessment

Treatment

### Clinical Specialty

Plastic Surgery

Surgery

#### **Intended Users**

Advanced Practice Nurses

Health Care Providers

Health Plans

Physician Assistants

Physicians

### Guideline Objective(s)

To address the assessment of symptomatic breast hypertrophy, its treatment through reduction mammaplasty, and to develop a set of recommendations that fairly reflect current accepted medical standards

### **Target Population**

Women with symptomatic breast hypertrophy

#### **Interventions and Practices Considered**

Diagnosis/Evaluation

- 1. Physical examination
- 2. Surgical planning, including breast volume removal, body mass index

Treatment/Management

- 1. Reduction mammaplasty
- 2. Use of perioperative antibiotics in reduction mammaplasty

Note: The use of drains in standard reduction mammaplasty was considered but not recommended; if liposuction is used as an adjunctive technique, the decision to use drains should be left to the surgeon's discretion.

### Major Outcomes Considered

- Physical and psychological symptoms
- Quality of life

## Methodology

#### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Literature Search and Admission of Evidence

A prospective, systematic method was used to identify current literature on the treatment of symptomatic breast hypertrophy. A comprehensive search of PubMed, the Cochrane Database of Systematic Reviews, and the Cumulative Index to Nursing and Allied Health Literature was performed by using various combinations of the following search terms: mammaplasty, reduction mammaplasty, breast reduction, breast hypertrophy, macromastia, as well as a wide range of indexing terms (MeSH terms), free text words and word variants. Search limits restricted results to English-language manuscripts that were indexed as human studies, randomized controlled trials, meta-analyses, clinical trials, or comparative studies. Articles were selected if they were relevant to clinical questions about risk factors, treatment, effectiveness/quality of life, and postoperative complications.

Additional references were included if deemed necessary for discussion; however, these references were neither critically appraised nor used for the development of practice recommendations. Details of literature search terms and search results for each clinical question are provided in Appendix B in the original guideline document.

#### Number of Source Documents

The literature search identified a total of 667 articles. After screening and critical appraisal, the results were narrowed to 22 relevant studies of high to moderate quality.

### Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

### Rating Scheme for the Strength of the Evidence

Evidence Rating Scale for Therapeutic Studies

| Level of<br>Evidence | Qualifying Studies  |
|----------------------|---|
| I                    | High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or systematic review of these studies                 |
| II                   | Lesser-quality, randomized controlled trial; prospective cohort or comparative study; or systematic review of these studies                             |
| III                  | Retrospective cohort or comparative study, case-control study; or systematic review of these studies  |
| IV                   | Case series with pre/post test; or only post test   |
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Evidence Rating Scale for Diagnostic Studies

| Level of<br>Evidence | Qualifying Studies  |
|----------------------|---|
| I                    | High-quality, multi-centered or single-centered, cohort study validating a diagnostic test (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies |

| Hevel of<br>Evidence | Republicates Studies to study developing diagnostic criteria (with "gold" standard as reference) in a series of consecutive patient; or a systematic review of these studies |
|----------------------|--|
| Ш                    | Diagnostic study in nonconsecutive patients (without consistently applied "gold" standard as reference); or a systematic review of these studies                             |
| IV                   | Case-control study; or any of the above diagnostic studies in the absence of a universally accepted "gold" standard  |
| V                    | Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or "first principles"                      |

Evidence Rating Scale for Prognostic/Risk Studies

| Level of<br>Evidence | Qualifying Studies  |
|----------------------|---|
| Ι                    | High-quality, multi-centered or single-centered, prospective cohort or comparative study with adequate power; or a systematic review of these studies   |
| II                   | Lesser-quality prospective cohort or comparative study; retrospective cohort or comparative study; untreated controls from a randomized controlled trial; or a systematic review of these studies |
| Ш                    | Case-control study; or systematic review of these studies   |
| IV                   | Case series with pre/post test; or only post test   |
| V                    | Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or "first principles"   |

### Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

### Description of the Methods Used to Analyze the Evidence

The American Society of Plastic Surgeons (ASPS) evidence-based process includes a rigorous critical appraisal process. Each article is appraised by at least two reviewers. If a discrepancy exists between the reviewers, the article is appraised by a third reviewer, and the level of evidence is determined by consensus. Articles are appraised with checklists appropriate for the clinical question (therapy, prognosis/risk, or diagnosis) and study design (randomized controlled trial [RCT], cohort/comparative, case-control, etc.). ASPS checklists are based on commonly used appraisal tools (e.g., Critical Appraisal Skills Programme [CASP] and the Centre for Evidence Based Medicine [CEBM]). Studies were assigned levels of evidence according to the ASPS Evidence Rating Scales for Therapy, Risk, and Diagnosis (see the "Rating Scheme for the Strength of the Evidence"). Evidence ratings were not assigned to studies with inadequately described methods and/or worrisome biases.

#### Methods Used to Formulate the Recommendations

**Expert Consensus** 

### Description of Methods Used to Formulate the Recommendations

Clinical questions were identified from a list of topics discussed in the 2002 version of this guideline:

• In patients with symptomatic breast hypertrophy, do women meeting common insurance coverage criteria for resection volume (compared to women not meeting common insurance coverage criteria) experience increased postoperative relief of breast hypertrophy related

- symptoms?
- In patients with symptomatic breast hypertrophy undergoing reduction mammaplasty, is large resection weight (compared to small resection weight) associated with higher risk of complications?
- In patients with symptomatic breast hypertrophy undergoing reduction mammaplasty, is high body mass index (BMI) >25, (compared to normal BMI, 18.5-24.9) associated with higher risk of complications?
- In patients with symptomatic breast hypertrophy undergoing reduction mammaplasty, does the use of perioperative antibiotic prophylaxis compared to no perioperative antibiotic prophylaxis reduce the risk of infection?
- In patients with symptomatic breast hypertrophy undergoing reduction mammaplasty, is a single preoperative dose of antibiotics compared to a perioperative course (24 hour period) effective at reducing the risk of infection?
- In patients with symptomatic breast hypertrophy undergoing reduction mammaplasty, does the use of drains (compared to no drains) decrease risk of complications?

The American Society of Plastic Surgeons (ASPS) Health Policy Committee sought to update previous practice recommendations with current evidence. Practice recommendations were developed through critical appraisal of the literature and consensus of the Committee. Recommendations are based on the strength of supporting evidence and were graded according to the ASPS Grades of Recommendation Scale (see the "Rating Scheme for the Strength of Recommendations" field).

### Rating Scheme for the Strength of the Recommendations

Scale for Grading Recommendations

| Grade | Description              | Qualifying Evidence   | Implications for Practice  |
|-------|--------------------------|---|--|
| A     | Strong<br>Recommendation | Level I evidence or<br>consistent findings<br>from multiple studies of<br>levels II, III, or IV | Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.   |
| В     | Recommendation           | Levels II, III, or IV<br>evidence and findings<br>are generally consistent                      | Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences.  |
| С     | Option                   | Levels II, III, or IV<br>evidence, but findings<br>are inconsistent                             | Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.                      |
| D     | Option                   | Level V: Little or no<br>systematic empirical<br>evidence                                       | Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role. |

### Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### Method of Guideline Validation

Internal Peer Review

### Description of Method of Guideline Validation

Members of the American Society of Plastic Surgeons (ASPS) Education and Health Quality and Advocacy Committees were invited to peer review this guideline. Peer reviewers were given two weeks to review this guideline using an abbreviated version of the Appraisal of Guidelines Research & Evaluation (AGREE) Instrument developed by the AGREE Collaboration. Forty Committee Members were invited to peer review the guideline and nineteen members responded to the online survey.

After the peer review process, the guideline draft was re-reviewed and modified by the ASPS Health Policy Committee. The final guideline draft was approved by the ASPS Executive Committee during their May 2011 meeting.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

#### **Potential Benefits**

Appropriate assessment and treatment of symptomatic breast hypertrophy through reduction mammaplasty

#### **Potential Harms**

- The findings that breast reduction may decrease the risk of breast cancer, especially in older women (≥40 years) and those with larger amounts of breast tissue removed per breast (≥600 g), are counterbalanced by the potential harms of reduction mammaplasty, including pain, bleeding, infections, scarring, seroma, hematoma, skin or fat necrosis, wound-healing complications, breast asymmetry, change or loss in nipple-areolar sensation, inability to breastfeed, abnormalities on mammography, and the potential to obscure lymphoscintigraphy for breast cancer sentinel node mapping.
- Complications of reduction mammaplasty may include the following:
  - Infection
  - Delayed wound healing
  - Wound dehiscence
  - Hematoma and/or seroma
  - Skin or nipple-areola necrosis
  - Fat necrosis
  - Cosmetic deformity
  - Unfavorable scarring
  - Alteration of nipple sensation
  - Thromboembolic complications
  - Inability to breastfeed
  - Need for revision surgery
  - Need for physical therapy
- Antibiotic prophylaxis poses the potential for allergic/anaphylactic reactions, the development of resistant bacteria, and increased costs, which may not be reimbursed by insurance companies.
- Using drains in standard reduction mammaplasty procedures may increase postoperative physical discomfort and breast pain, pinching at drain exit site, painful drain removal, and drain exit scar.

See the original guideline document for more detailed information on the complications of reduction mammaplasty.

## **Qualifying Statements**

## Qualifying Statements

• Evidence-based guidelines are strategies for patient management, developed to assist physicians in clinical decision making. This guideline, based on a thorough evaluation of the scientific literature and relevant clinical experience, describes a range of generally acceptable

- approaches to diagnosis, management, or prevent specific diseases or conditions. This guideline attempts to define principles of practice that should generally meet the needs of most patients in most circumstances.
- This guideline should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all the circumstances presented by the patient, the diagnostic and treatment options available and available resources.
- This guideline is not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all
  the facts or circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance, and as
  practice patterns evolve. This guideline reflects the state of knowledge current at the time of publication. Given the inevitable changes in the
  state of scientific information and technology, periodic review, updating and revision will be done.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Patient Resources

Staff Training/Competency Material

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

**IOM Care Need** 

Getting Better

#### **IOM Domain**

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

American Society of Plastic Surgeons. Evidence-based clinical practice guideline: reduction mammaplasty. Arlington Heights (IL): American Society of Plastic Surgeons; 2011 May. 16 p. [33 references]

### Adaptation

The guideline was not adapted from another source.

#### Date Released

2011 May

### Guideline Developer(s)

American Society of Plastic Surgeons - Medical Specialty Society

### Source(s) of Funding

American Society of Plastic Surgeons

#### Guideline Committee

Health Policy Committee of the American Society of Plastic Surgeons

### Composition of Group That Authored the Guideline

Committee Members: Loree Kalliainen, M.D. (Chair); Dale C. Vidal, M.D. (Past Chair); Peter Aldea, M.D.; Steven Bonawitz, M.D.; Gary Culbertson, M.D.; Kevin Chung, M.D.; Lynn Damitz, M.D.; Leland Deane, M.D.; Richard Greco, M.D.; Christopher Hussussian, M.D.; Sami Khan, M.D.; Bill Kortesis, M.D.; Gordon Lee, M.D.; Stephen Metzinger, M.D.; Galen Perdikis, M.D.; Adam Ravin, M.D.; Neal Reisman, M.D.; Karie Rosolowski, M.P.H.; Loren Schechter, M.D.; DeLaine Schmitz, R.N, M.S.H.L; Alexander Spiess, M.D.; Jennifer Swanson, M.Ed.; William Wooden, M.D.

#### Financial Disclosures/Conflicts of Interest

All contributors and preparers of the guideline, including the American Society of Plastic Surgeons (ASPS) Health Policy Committee and staff, disclosed any conflicts of interest via an online disclosure reporting database.

Loree Kalliainen, M.D. (*Chair*), has no additional disclosures; Dale C. Vidal, M.D. (*Past Chair*), has a Consultant relationship with Mentor Corporation/Ethicon/J&J; Peter Aldea, M.D., has no additional disclosures; Steven Bonawitz, M.D., has no additional disclosures; Gary Culbertson, M.D., has no additional disclosures; Kevin Chung, M.D., has no additional disclosures; Lynn Damitz, M.D., has no additional disclosures; Leland Deane, M.D., has a consultant relationship with Covidien; Richard Greco, M.D., has a speaker relationship with Mentor Corporation/Ethicon/J&J and a shareholder relationship with Obagi Medical Products; Christopher Hussussian, M.D., has no additional disclosures; Sami Khan, M.D., has no additional disclosures; Bill Kortesis, M.D., has no additional disclosures; Gordon Lee, M.D., has a consultant relationship with Covidien, Inc., LifeCell Corporation/KCI, and TEI, Inc.; Stephen Metzinger, M.D., has no additional disclosures; Galen Perdikis, M.D., has no additional disclosures; Adam Ravin, M.D., has no additional disclosures; Neal Reisman, M.D., has no additional disclosures; Karie Rosolowski, M.P.H., has no additional disclosures; Loren Schechter, M.D., has no additional disclosures; DeLaine Schmitz, R.N, M.S.H.L, has no additional disclosures; Alexander Spiess, M.D., has no additional disclosures; Jennifer Swanson, M.Ed., has no additional disclosures; William Wooden, M.D., has no additional disclosures

#### Guideline Status

This is the current release of the guideline.

### Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the American Society of Plastic Surgeons Web site

| Print copies: Available from the American Society of Plastic Surgeons, 444 East Algonquin Road, Arlington Heights, IL 6005-4664   |
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| Availability of Companion Documents   |
| The following is available:   |
| Breast reconstruction physician's counseling guide. Breast mammaplasty. Arlington Heights (IL): American Society of Plastic Surgeons (ASPS). Available from the ASPS Web site.  |
| Patient Resources   |
| The following is available:   |
| Breast reduction. Reduction mammaplasty. Brochure. Arlington Heights (IL): American Society of Plastic Surgeons (ASPS); 2007. 16 p.  Available in Portable Document Format (PDF) from the ASPS Web site   |
| In addition, a variety of patient resources on reduction mammaplasty, including information on the risks and safety of breast reduction, surgery results and costs, and choosing a surgeon, as well as an overview video, are available from the ASPS Web site.   |
| Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content. |
| NGC Status  |
| This NGC summary was completed by ECRI Institute on September 26, 2011. The information was verified by the guideline developer on October 28, 2011.  |
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